

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

In re:	)	MDL No. 1456
	)	Civil Action No. 01-12257-PBS
PHARMACEUTICAL INDUSTRY	)	Subcategory No. 06-11337
AVERAGE WHOLESAL PRICE	)	
LITIGATION	)	Hon. Patti B. Saris
	)	
_____	)	
	)	
<b>THIS DOCUMENT RELATES TO:</b>	)	
	)	
<i>United States ex rel Ven-A-Care of the</i>	)	
<i>Florida Keys, Inc. v. Schering Corporation,</i>	)	
<i>Schering-Plough Corporation and</i>	)	
<i>Warrick Pharmaceuticals Corporation</i>	)	
Civil Action No. 09-CV-10547	)	
	)	
<i>United States ex rel Ven-A-Care of the</i>	)	
<i>Florida Keys, Inc. v. Schering Corporation,</i>	)	
<i>Schering-Plough Corporation and</i>	)	
<i>Warrick Pharmaceuticals Corporation</i>	)	
Civil Action No. 00-10698	)	

**PRELIMINARY RESPONSE BY SCHERING-PLOUGH CORPORATION, SCHERING  
CORPORATION, AND WARRICK PHARMACEUTICALS CORPORATION TO THE  
UNITED STATES'S OBJECTION TO THE PROPOSED SETTLEMENT AND  
PROPOSED ORDER**

Defendants Schering Corporation, Schering-Plough Corporation, and Warrick Pharmaceuticals Corporation (collectively "Schering/Warrick"), hereby provide this preliminary response to the United States's Objection to the Proposed Settlement Between Schering-Plough Corporation, Schering Corporation, Warrick Pharmaceuticals Corporation and Ven-A-Care of the Florida Keys, and Proposed Order (the "Objection").

The Objection highlights the nature and extent of the roadblocks placed by the Department of Justice ("DOJ") in the path of a comprehensive resolution of this (and other) longstanding AWP-related cases. Astonishingly, after investigating and declining to intervene

in this matter in late 2008 – after the case(s) had been pending for fourteen years – the United States now suggests that its declination was motivated, in part, by a preference for piecemeal resolution of this controversy. Notwithstanding that the Relator has pursued claims for the entire federal share for many years, DOJ now reveals its position that the parallel claims by some (but not all) states should frustrate a comprehensive resolution of the federal-share claims in this case, as well as any hope of repose for Schering/Warrick. See Objection ¶ 2.<sup>1</sup> While DOJ may prefer to "sit on the sidelines" while parallel claims for the federal share are litigated on its behalf in state and federal courts, the settlement experience over nearly eight years in this MDL proceeding underscores the intolerable burden that DOJ's approach has imposed on the defendants (and, in our view, on the Court).

In its effort to sustain its piecemeal approach, DOJ raises legal questions about the "scope of the release" implied by the Settlement, including whether the Settlement properly includes both brand and generic drugs, whether the Court has "jurisdiction" as an Article III court after years of litigation to address the factual findings upon which a portion of the Settlement rests, and whether the claims can be dismissed "with prejudice" over DOJ's objections. See Objection ¶¶ 3, 4. The Settlement anticipates each of these DOJ objections, and Schering/Warrick is eager to establish the reasonableness of the settlement structure and amount, and to explain the statutory, constitutional, and public policy basis for the Court's authority to approve the Settlement under the compelling circumstances presented here. Schering/Warrick will present a proposal for addressing these issues in a expeditious manner at the status conference on July 24.

One factual assertion by DOJ requires a response. The Objection complains that DOJ has not conducted an "investigation" of the claims involving Schering's brand drugs. See Objection

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<sup>1</sup> "Indeed, the Government declined to intervene against Schering/Warrick, in part, because it knew that several states had sued Schering/Warrick for the Covered Conduct and were presumably pursuing both the federal and state shares of their respective state's Medicaid damages."

¶ 3. This is preposterous. Schering has had extensive discussions over the years with DOJ in connection with its consideration whether to intervene in these cases, and those discussions have included comprehensive attention to the brand drugs, as well as to the generic drugs. In fact, **at DOJ's request**, the expert analyses, underlying data, and other information bearing on the reasonableness of the treatment of brand drugs in the Settlement were provided to DOJ in February of 2008, well before DOJ elected not to intervene. Not once in the year-and-a-half since, has DOJ ever asserted that it lacked any information from Schering or Warrick, nor has it requested any data or other information since the Settlement with the Relator was filed with the Court. In any event, Exhibit A reflects a detailed analysis prepared by Dr. Sumanth Addanki, and to the extent that the court deems it appropriate, Schering/Warrick would be pleased to make Dr. Addanki available for an evidentiary hearing.

Respectfully submitted,

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Dated: July 22, 2009

**CERTIFICATE OF SERVICE**

I hereby certify that on July 22, a true copy of the above Preliminary Response was served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

July 22, 2009

/s/ John P. Bueker  
John P. Bueker